

APPENDIX B

AIPA Term Calculation Report

| APPLICATION INFORMATION | | | |
|-------------------------|--|--------------------|-----------------------------|
| Docket Number: | CV01679 | User Name: | MackMillan, Keith |
| Application Number: | 10/701,244 | Firm/Company Name: | Schering-Plough Corporation |
| Filing Date: | 11/04/2003 | User Comments: | |
| Title/Inventor(s): | METHODS AND THERAPEUTIC COMBINATIONS FOR THE TREATMENT OF DEMYELINATION; Jay S. Fine, Bloomfield, NJ | | Calculation Generated: |
| | | | 08/25/2009 09:53:11 AM ET |

| AIPA TERM CALCULATION SUMMARY | | | |
|---|--|--------------------|--|
| Earliest Referenced Application under 35 USC § 120, 121, or 365(c): | | 11 / 06 / 2002 | |
| Filing Date (US National Application): | | 11 / 04 / 2003 | |
| Net Adjustment Credits: | | 868 Days | |
| Net Adjustment Debits: | | 0 Days | |
| Patent Term Adjustment: | | 868 Days | |
| AIPA Patent Term End Date: | | 03 / 23 / 2025 (1) | |
| (1) Assumes payment of all maintenance fees, no intervening acts, and no 35 USC 156 regulatory extensions. Terminal disclaimer(s) filed in this case, if any, may result in an earlier term end date. Without adjustment, the term would end on 11/06/2022. | | | |

| COMPARISON TO USPTO PAIR PTA TAB (2) (Based on PAIR Data from 08/25/2009) | | | |
|--|--------------|------------------|------------|
| | PAIR PTA Tab | Your Calculation | Comparison |
| Credit Days (USPTO Delay): | 868 | 868 | March |
| Debit Days (Applicant Delay): | 0 | 0 | March |
| Total Patent Term Adjustment Days: | 868 | 868 | March |

(2) Comparison is shown for USPTO Delay, Applicant Delay, and Total Patent Term Adjustment fields displayed on USPTO PAIR Patent Term Adjustments (PTA) tab on 08/25/2009. See the full PAIR PTA tab file wrapper (e.g., Notice of Allowance, PTA-related petitions), and issued patent for complete information on USPTO-calculated PTA.

RULE CALCULATION SUMMARY (3)

| Event | Rule Invoked | Related Event | Exclusion Days (4) | Debit Days (5) | Credit Days (6) |
|---|---|--|--------------------|----------------|-----------------|
| <p>11/04/2003 Filing Date under 35 USC 111(a) (US National Application)</p> | <p align="center">14-Month PTO First Action</p> <p>PTO must mail a notification under 35 USC 132 or a notice of allowance under 35 USC 151 not later than 14 months after the date on which the application was filed under 35 USC 111(a) or fulfilled the requirements of 35 USC 371 in an international application. Period of adjustment (credits) begins on the day after the date that is 14 months after the date on which the application was filed under 35 USC 111(a) or fulfilled the requirements of 35 USC 371 and ending on the date of mailing of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(i); 37 CFR 1.702(a)(1), 1.703(a)(1).</p> | <p><i>First PTO Action:</i> 04/12/2007 Restriction / Election-of-Species</p> | | | 828 |
| <p>11/04/2003 Filing Date under 35 USC 111(a) (US National Application)</p> | <p align="center">3-Year PTO Issue of Patent</p> <p>PTO must issue a patent within 3 years (not including exclusions) after the date on which the application was filed under 35 USC 111(a) or the national stage commenced under 35 USC 371(b) or (f) in an international application. Period of adjustment (credits) begins on the day after the date that is 3 years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 USC 371(b) or (f) in an international application and ending on the date a patent was issued, but not including the sum of the listed exclusionary periods. 35 USC 154(b)(1)(B); 37 CFR 1.702(b), 1.703(b).</p> <p>You have elected to analyze this rule under the USPTO 37 CFR § 1.703(f) Actual Delay Limitation. Note, however, this interpretation was overturned by the DC District Court in Wyeth et al. v. Dudas, No. 07-1492 (D.D.C. September 30, 2008). Credit Days shown for this rule are those remaining after the Actual Delay Limitation is applied. See separate calculation details below. If you are viewing an AIPA Term Calculation Calendar, note that the calendar months show marks for all credits under this rule, even those eliminated under this election.</p> | <p><i>Issue Date:</i> 07/14/2009 Issue Date</p> | | | 0 |
| <p>04/12/2007 Restriction / Election-of-Species</p> | <p align="center">3-Month Applicant Response to Notice or Action</p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c).</p> <p>You have indicated that no 1.705(c) Showing of Due Care was made.</p> | <p><i>Applicant Response:</i> 05/11/2007 Response to Election-of-Species / Restriction Filed</p> | | 0 | |

| | | | | |
|---|--|--|----------|----------|
| <p>D</p> <p>05/11/2007 Response to Election-of-Species / Restriction Filed</p> | <p>4-Month PTO Response to Applicant Reply</p> <p>PTO must respond to a reply under 35 USC 132 not later than 4 months after the date on which the reply was filed. The period of adjustment (credits) begins on the day after the date that is 4 months after the date a reply under 37 CFR 1.111 or in compliance with 37 CFR 1.113(c) was filed and ending on the mailing date of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(ii); 37 CFR 1.702(a)(2), 1.703(a)(2),(3).</p> | <p><i>PTO Response:</i> 07/27/2007 Non-final Action</p> | | <p>0</p> |
| <p>E</p> <p>07/27/2007 Non-final Action</p> | <p>3-Month Applicant Response to Notice or Action</p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c).</p> <p>You have indicated that no 1.705(c) Showing of Due Care was made.</p> | <p><i>Applicant Response:</i> 10/26/2007 Reply after Non-final Action under 37 CFR 1.111</p> | <p>0</p> | |
| <p>F</p> <p>10/26/2007 Reply after Non-final Action under 37 CFR 1.111</p> | <p>4-Month PTO Response to Applicant Reply</p> <p>PTO must respond to a reply under 35 USC 132 not later than 4 months after the date on which the reply was filed. The period of adjustment (credits) begins on the day after the date that is 4 months after the date a reply under 37 CFR 1.111 or in compliance with 37 CFR 1.113(c) was filed and ending on the mailing date of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(ii); 37 CFR 1.702(a)(2), 1.703(a)(2),(3).</p> | <p><i>PTO Response:</i> 11/16/2007 Notice of Allowance under 35 USC 151</p> | | <p>0</p> |
| <p>G</p> <p>11/16/2007 Notice of Allowance under 35 USC 151</p> | <p>3-Month Applicant Response to Notice or Action</p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c).</p> <p>You have indicated that no 1.705(c) Showing of Due Care was made.</p> | <p><i>Applicant Response:</i> 02/15/2008 Issue Fee Payment under 35 USC 151</p> | <p>0</p> | |

| | | <u>Exclusion for Continued Examination</u> | | | |
|---|--|--|--|-----|--|
| H | 09/26/2008 Request for Continued Examination under 35 U.S.C. 132(b) | 3-Year PTO Issue Requirement does not include the period consumed by continued examination of the application under 35 USC 132(b), beginning on the date on which a request for continued examination of the application under 35 USC 132(b) was filed and ending on the date the patent was issued. 35 USC 154(b)(1)(B)(i); 37 CFR 1.702(b)(1), 1.703(b)(1). | <i>Issue Date:</i> 07/14/2009 Issue Date | 292 | |
| | | 3-Month Applicant Response to Notice or Action | | | |
| I | 11/10/2008 Notice of Allowance under 35 USC 151 | Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b). Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c). You have indicated that no 1.705(c) Showing of Due Care was made. | <i>Applicant Response:</i> 02/04/2009 Issue Fee Payment under 35 USC 151 | 0 | |
| J | 02/04/2009 Issue Fee Payment under 35 USC 151 | PTO must issue a patent not later than 4 months after the date on which the issue fee was paid under 35 USC 151 and all outstanding requirements were satisfied. The period of adjustment (credits) begins on the day after the date that is 4 months after the date the issue fee was paid and all outstanding requirements were satisfied and ends on the day the patent issues. 35 USC 154(b)(1)(A)(iv); 37 CFR 1.702(a)(4), 1.703(a)(6). | <i>Issue Date:</i> 07/14/2009 Issue Date | 40 | |
| Total Exclusion, Debit, and Credit Days: | | 292 | 0 | 868 | |
| Overlap Days (7) : | | 0 | 0 | 0 | |
| Net Exclusion, Debit, and Credit Days: | | 292 | 0 | 868 | |
| Patent Term Adjustment Days (8) : | | | | 868 | |

(3) Calculations of Debit, Credit, and Exclusion Days are determined by the rule assignments, assignments of related events, and analysis options in the Apply Term Rules tab. The patent professional using this system is responsible for reviewing and updating the Apply Term Rules tab to ensure all data is complete, correct, and consistent with their judgment and interpretation of applicable legal authority.

(4) Exclusion Days are periods which are not included in determining the end of the 3-year period after the date on which the application was filed under 35 USC 111(a), or the national stage commenced under 35 USC 371(b) or (f) in an international application, used to determine credits under the 3-Year PTO Issue of Patent rule. See 35 USC 154(b)(1)(B)(i)-(iii); 37 CFR 1.702(b)(1)-(5), 1.703(b)(1)-(4).

(5) Debit Days are days where grounds for reduction of period of adjustment of patent term exist. See, e.g., 37 CFR 1.704. Debit Days are sometimes referred to as Applicant Delay.

(6) Credit Days are days where grounds for adjustment of patent term exist. See, e.g., 37 CFR 1.702, 1.703. Credit Days are sometimes referred to as USPTO Delay.

(7) To the extent credit periods overlap other credit periods, debit periods overlap other debit periods, or exclusion periods overlap other exclusion periods, overlaps are subtracted so that each calendar day generates at most one credit day, one debit day, and one exclusion day.

(8) Patent Term Adjustment Days equals Net Credit Days minus Net Debit Days, but is not less than zero.

37 CFR § 1.703(f) "ACTUAL DELAY" LIMITATION CALCULATION

| | Credit Days |
|--|-------------|
| Number of days issue of patent exceeded 3 years after the date on which the application was filed under 35 USC 111(a) or the national stage commenced under 35 USC 371(b) or (f) in an international application, not including exclusion days (4) : | 691 |
| Number of Net Credit Days (6) from all rules other than 3-Year PTO Issue of Patent rule, not including Credit Days on exclusion days (4) : | 828 |
| Remaining Credit Days generated under 3-Year PTO Issue of Patent rule, after 37 CFR 1.703(f) Actual Delay Limitation: | 0 |